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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : David J Pinsky, et al.

U.S. Serial No.: 09/671,100 Examiner: A. DeCloux

Filed : September 27, 2000 Group Art Unit: 1644

For : METHODS FOR TREATING ISCHEMIC DISORDER AND IMPROVING STROKE OUTCOME

1185 Avenue of the Americas
New York, New York 10036
October 29, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO AUGUST 29, 2001 OFFICE ACTION AND PETITION FOR A ONE-MONTH EXTENSION

This Communication is submitted in response to an August 29, 2001 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A Response to the August 29, 2001 Office Action was originally due September 29, 2001. Applicants hereby petition for a one-month extension of time. Applicants have previously established small entity status. The required fee for a one-month extension of time for a small entity is $55.00 and applicants enclose a check to cover this fee. Therefore, a response is due October 29, 2001. Accordingly, this Communication is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

The Examiner required restriction to one of the following

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inventions under 35 U.S.C. §121:

I. Claims 1-20, allegedly drawn to a method for treating an ischemic disorder comprising administrating a Factor Ixa compound classified in class 514, subclasses 12 and 44,

II. Claims 21-24, allegedly drawn to a method for identifying a compound that is capable of improving an ischemic disorder, classified in Class 424 subclass 9.2,

III. Claims 25-28, allegedly drawn to a method for treating a reperfusion injury comprising administering a Factor Ixa compound, classified in class 514, subclasses 12 and 44,

IV. Claims 29-30, allegedly drawn to method of inhibiting clot formation comprising administering an inactive recombinant mutein, classified in Class 514, subclass 2,

V. Claims 31-32, allegedly drawn to an assay to monitor the effect of a Factor Ixa compound, classified in Class 435, subclass 4.

The Examiner stated that the inventions are distinct, each from the other because: The Examiner alleged that Groups I-V are unique methods. The Examiner stated that the ingredients, process steps and endpoints of Group II differ from those of Groups I/III/IV since Group II is drawn to a method for identifying a compound that is capable of improving an ischemic disorder while Groups I/III/IV are each drawn to a treatment method. The Examiner stated that the endpoint (a method of

inhibiting clot formation) and the process steps (comprising administering a Factor Ixa compound) but differ with respect to their endpoints (treating an ischemic disorder) vs (treating a reperfusion injury), respectively. The Examiner stated that the endpoint of Group V is distinct from that of Groups I/III and IV since monitoring is distinct from treating and inhibiting clot formation, respectively. The Examiner stated that Group V is distinct from Group II since the resolution steps of each group are different. Therefore, the Examiner stated that Groups I-V are patentably distinct each from the other.

The Examiner stated that because inventions I-V are distinct for the reasons given above, and they have acquired a separate status in the art because the searches of the non patent literature are not co-extensive an encompass divergent subject matter, restriction for examination purposes as indicated is proper.

The Examiner stated that if Group I-III or V is elected, the applicant is further required under 35 U.S.C. 121: to elect a **specific Factor Ixa compound** such as one recited in claim 4 or claim 27.

The Examiner stated that if Group I or V is elected, the applicant is further required to elect a **specific ischemic disorder** such as one recited in claim 7.

The Examiner stated that if Group II or V is elected, the applicant is further required to elect a **specific means of measuring stroke outcome** such as one recited in claim 24 or claim

32, respectively.

The Examiner stated that if Group I is elected, the applicant is further required:

A) to elect a **specific indirect fibrinolytic agent**, such as one recited in claim 20,

B) to elect a **specific direct firbrinolytic agent,** such as one recited in claim 19,

C) to elect a **specific surgery,** such as one recited in claim 9,

I) if organ transplantation surgery is elected then applicant is further required to elect a **specific organ surgery,** such as one recited in claim 10,

D) to elect a **specific period of time**, such as one recited in claims 11-14.

The Examiner stated that applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The Examiner stated that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim

as provided by 37 CFR 1.141. The Examiner stated that if claims are added after the election, applicant must indicate which are readable upon the elected species. The Examiner stated to see MPEP §809.02(a).

The Examiner stated that should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

The Examiner stated that the following claim(s) are generic: claims 1-28 and 31-32.

The Examiner stated that the species are distinct each from the other for the following reasons: A) the recited Factor Ixa compounds, indirect fibrinolytic agents, and direct fibrinolytic agents each have distinct biophysical properties and structures and therefore a disclosure showing treating, identifying or assaying with another recited compound, indirect fibrinolytic agent, or direct fibrinolytic agent, respectively. B) The recited surgery, and the recited organ surgery each have distinct process steps and procedures. C) The recited means of measuring stroke outcome each have distinct process steps and procedures. D) The recited ischemic disorders each have distinct symptoms and etiologies. E) The recited period of times of administration

each have distinct process and method steps with conceivably outcomes

The Examiner stated that applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

The Examiner stated that because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The Examiner stated that applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

In response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, to prosecute the invention of Examiner's Group I, i.e. claims 1-20 , allegedly drawn to a method for treating an ischemic disorder comprising administering a Factor IXa compound, classified in class 514, subclasses 12 and 44.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction of Examiner's Group I from Examiner's Groups II-V be withdrawn in view of the fact that the claims of Examiner's Group I are not independent of Examiner's Groups II-V. Applicant maintains that the claims of Examiner's Group I and Examiner's Groups II-V do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group I, allegedly drawn to a method for treating an ischemic disorder comprising administering a Factor IXa is related to the claims of Examiner's Groups II-V in that the claims in all groups are directly related to a Factor IXa compound.

The claims of Examiner's Group I, allegedly drawn to a method for treating an ischemic disorder comprising administering a Factor IXa compound is related to the claims of Examiner's Group III, allegedly drawn to a method for treating a reperfusion injury comprising administering a Factor IXa compound and Group IV, allegedly drawn to a method of inhibiting clot formation comprising administering an inactive recombinant mutein, because of the reliance of all identified claims of Groups I, III and IV on the use of a Factor IXa compound as part of their design,

operation, and effect. The specification teaches at page 19, lines 3-11, that the "ischemic disorder" encompasses and is not limited to a peripheral vascular disorder, a venous thrombosis, a pulmonary embolus, a myocardial infarction, a transient ischemic attack, lung ischemia, unstable angina, a reversible ischemic neurological deficit, adjunct thrombolytic activity, excessive clotting conditions, reperfusion injury, sickle cell anemia, a stroke disorder or an iatrogenically induced ischemic period such as angioplasty. The specification teaches at page 19, lines 26-28 that Factor IXa acts specifically as a serine protease which, when complexed with VIIIa on membrane surfaces, converts Factor X to its active form Xa, thus promoting coagulation through the intrinsic pathway. Further, the specification also teaches at page 4, lines 7-13, that the present invention provides a method for treating an ischemic disorder in a subject by administering to the subject an inactivated Factor IXa to inhibit coagulation so as to treat the "ischemic disorder" in the subject. Therefore, Examiner's Group I, allegedly drawn to a method for treating an "ischemic disorder" comprising administering a Factor IXa compound, Examiner's Group III, allegedly drawn to a method for treating a reperfusion injury comprising administering a Factor IXa compound and Group IV, allegedly drawn to a method of inhibiting clot formation comprising administering an inactive recombinant mutein, utilize a Factor IX a compound to inhibit coagulation as part of their design, operation, and effect. Accordingly, applicants request that the Examiner examine Groups I, III and IV on the merits.

The claims of Examiner's Group II, allegedly drawn to a method for identifying a compound that is capable of improving an ischemic disorder, and Group V allegedly drawn to an assay to monitor the effect of a Factor IXa compound, are related because of the shared structural and functional relationship of agents used to inhibit Factor IXa and the intrinsic clotting pathway identified in all claims in Groups II and V. The claims of Examiner's Group I, allegedly drawn to a method for treating an ischemic disorder comprising administering a Factor IXa compound, may use a compound that is capable of improving an ischemic disorder as identified by an assay to monitor the effect of a Factor IXa compound of Examiner's Groups II and V as part of its overall design, operation and effect. Therefore, the claims of Examiner's Groups I, II and V are related. Accordingly, Examiner's Groups II and V are related to Groups III and IV through their respective relaion to the claims of Group I.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND

(2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group I, claims 1-20 allegedly drawn to a method for treating an ischemic disorder comprising administering a Factor IXa compound will reveal whether any prior art exists as to a method for identifying a compound that is capable of improving an ischemic disorder(Group II) and a method for treating a reperfusion injury comprising administering a Factor IXa compound(Group III), a method of inhibiting clot formation comprising administering an inactive recombinant mutein(Group IV) and an assay to monitor the effect of a Factor IXa compound(Group V). Since there is no burden on the Examiner to examine Groups I-V in the subject application, the Examiner must examine the entire application on the merits.

Applicant maintains that claims 1-32 define a single inventive concept. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-32 on the merits.

In addition, in response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, the following species:

1) Species of Factor IXa: a mutein;
2) Species of ischemic disorder: a peripheral vascular disorder;
3) Species of specific indirect fibrinolytic agent: recombinant

tissue plasminogen activator;

4) Species of specific direct fibrinolytic agent: plasmin;

5) Species of specific surgery: vascular surgery; and

6) Speices of a specific period of time: from about 5 days before surgery or onset of the disorder to about 5 days after surgery or the onset of the disorder.

In addition, applicants request that upon the allowance of a generic claim, consideration of claims to additional species which are written in dependent form be considered.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invite the Examiner to telephone him at the number provided below.

No fee other that the enclosed $55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

10/29/01

John P. White — Date
Reg. No. 28,678